

U.S. Application No. 09/853,581
Amendment dated February 14, 2005
In reply to the final office action of December 14, 2004
Attorney Ref. No.: 037003 - 0280617

II. REMARKS

Preliminary Remarks:

Claims 44, 48, 52, 53, 57, and 62-64 are amended, and claim 47 is canceled.

Claim 44 is amended to specify that the at least one TGF β -neutralizing agent is selected from the group consisting of an anti- β antibody, a TGF β R-fusion protein, a TGF β analog, a TGF β binding protein, and a TGF β R blocking antibody. This feature is incorporated from claim 47; accordingly, claim 47 is canceled, and claim 48 is amended to depend on claim 44 rather than on claim 47.

Claim 52 is amended to depend on claim 51.

Claims 53, 57, and 62 are amended to refer to the specified compounds by their chemical descriptions.

Claims 63 and 64 are amended to specify that the immunostimulating peptide to which the claims refer is muramyl dipeptide, as described, on page 12, lines 11-14.

Patentability Remarks:

Objections

The official action objected to claim 52 as being ambiguity because it depended on itself. The dependence of claim 52 on itself was a typographic error, which has been corrected by amending claim 52 to depend on claim 51.

35 U.S.C. §112, Second Paragraph

Claims 53, 57, and 62 were rejected under 35 U.S.C. §112, Second Paragraph, because they contain references to trademarked product names. The chemical names of the trademarked detergent and PEG products specified in claims 53, 57, and 62 are identified in the following table:

Product name	Technical/chemical name
Tween 20	polyoxyethylene sorbitan monolaurate
Tween 40	polyoxyethylene sorbitan monopalmitate

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Tween 60	polyoxyethylene sorbitan monostearate
Tween 80 (Polysorbate 80)	polyoxyethylene sorbitan monooleate
Zwittergent 3-12	<i>n</i> -dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate
Teepol HB7	secondary sodium alkyl sulfate
Span 85	sorbitane trioleate
PEG 1000	polyethylene glycol, average mol. wt. = about 1000

The trademarked pluronic compounds specified in claims 57 and 63 are block copolymers consisting of two ethylene oxide (EO) block polymers, each joined to a different end of a propylene oxide (PO) block polymer which have an approximate molecular weight and constitute the weight fraction of the total compound molecular weight as shown in the table below.

The trademarked tetronic compounds specified in claim 57 are tetrafunctional block copolymers consisting of ethylenediamine, the two nitrogens of which are each attached to two PO block polymers, each of which is in turn attached to an EO block polymer, wherein the constituent PO block polymers have an approximate combined molecular weight and constitute the weight fraction of the total molecular weight as shown in the table below.

Similarly, the trademarked tetronic R compounds specified in claim 57 are tetrafunctional block copolymers consisting of ethylenediamine, the two nitrogens of which are each attached to two EO block polymers, each of which is in turn attached to a PO block polymer, wherein the constituent PO block polymers have an approximate combined molecular weight and constitute the weight fraction of the total molecular weight as shown in the table below. (See U.S. Patent No. 6,218,438 B1; columns 11-15)

micelle-forming agent	Approx. hydrophobe (PO) molecular weight	Approx. hydrophobe wt. % of the total molecular weight
Pluronic L121 (poloxamer 401)	3956	90 %
Pluronic L62LF	2000	80 %
Pluronic L101	3416	90 %
Pluronic L64	1740	60 %
Tetronic 1501	7000	90 %

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Tetronic 150R1	6700	90 %
Tetronic 701	2200	90 %
Tetronic 901	3300	90 %
Tetronic 1301	5500	90 %
Tetronic 130R1	5700	90 %

Claims 53, 57, and 62 are amended to refer to the specified compounds by the above-identified chemical descriptions. Accordingly, withdrawal of the rejection of claims 53, 57, and 62 under 35 U.S.C. §112, Second Paragraph, is respectfully requested.

35 U.S.C. §112, First Paragraph

Claims 63-64 were rejected under 35 U.S.C. §112, First Paragraph, because the specification is considered to lack written description of the invention of claims 63 and 64 except wherein the immunostimulating peptide is muramyl dipeptide. Claims 63-64 have been amended to specify that the immunostimulating peptide is muramyl dipeptide, and withdrawal of the rejection under 35 U.S.C. §112, First Paragraph, is respectfully requested.

35 U.S.C. § 103(a)

Claims 44-46 and 49-64 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Raychaudhuri et al. (U.S. Patent No. 5,695,770), in combination with Berd et al. (U.S. Patent Application No. 2002/0004052) and Berd et al. (Cancer Research, Vol. 46, May 1986, pp. 2572-7), for the reasons of record.

Claims 47-48 were objected to as being dependent upon a rejected base claim, but would be considered allowable if re-written in independent form, including all of the limitations of the base claim and any intervening claims.

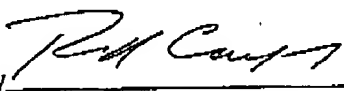
Claim 44 has been amended to incorporate from claim 47 the feature that the at least one TGF β -neutralizing agent is selected from the group consisting of an anti-TGF β antibody, a TGF β R-fusion protein, a TGF β analog, a TGF β binding protein, and a TGF β R blocking antibody. In addition, claim 47 is canceled, and claim 48 is amended to depend on claim 44 rather than on claim 47. Withdrawal of the rejection of claim 44-46 and 49-64 under 35 U.S.C. § 103(a), and the objection to claims 47 and 48, is respectfully requested.

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Conclusion

All rejections and objections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If any points remain in issue, which the examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,
PILLSBURY WINTHROP, LLP

By 
Thomas A. Cawley, Jr., Ph.D.
Reg. No.: 40944
Tel. No.: (703) 905-2144
Fax No.: (703) 905-2500

PILLSBURY WINTHROP LLP
P.O. Box 10500
McLean, VA 22102